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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,598	07/16/2003	Kwang-Sup Soh	912-38	6541

23117 7590 09/14/2006

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EXAMINER	
LEACH, CRYSTAL I	

ART UNIT	PAPER NUMBER
3737	

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/619,598	SOH ET AL.	
	Examiner	Art Unit	
	Crystal I. Leach	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☒ Claim(s) *1-14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *7/16/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. The non-patent literature reference listed on p.9 of the specification submitted on July 16, 2003 should be properly listed on an IDS form.

Claim Objections

2. Claims 1-14 are objected to because of the following informalities:

3. Regarding claims 1-14, the preamble and the body of the claims state detection of luminescence of two different objects. The preamble of the claims states “detecting luminescence from biological systems.” However, the body of the claims refers to detection of luminescence from “biological samples”. This creates inconsistency between the preamble and body of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether claim 1 is intending to claim the biological sample. For examination purposes, claim 1 will be examined as if the biological sample is not being claimed. Examiner will interpret claim as:

> 1. An apparatus for detecting luminescence from biological systems in response to magnetic fields comprising: a magnetic field generator adapted to be placed adjacent to a biological sample and generates a magnetic field adapted to be impressed on said biological sample; a photodetector which detects luminescence from said biological sample on which magnetic field is adapted to be impressed by said magnetic field generator; and a dark box adapted to shield said biological sample from external light.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-8, 10-12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Wohlstadter et al. (US 2001/0021534).

7. Regarding claim 1, Wohlstadter et al. teach a magnetic field generator in the form of a support (10) (pp. 27, [0172]), a photodetector means (68) (pp. 22, [0314]), and a light-tight box (pp.54, [0700]).

8. Regarding claim 2, Wohlstadter et al. disclose that the analyte of interest in a biological sample may be a whole cell (pp. 26, [0354]) and that the sample may be derived from body fluids or tissues (pp. 27, [0355]).

9. Regarding claim 3, Wohlstadter et al. teach a temperature control means (pp. 24, [0331]).

10. Regarding claims 4 and 5, Wohlstadter et al. teach a microfluidics guide which uses a syringe to deliver ECL labeled binding reagents and/or analytes to discrete binding domains (pp. 3, [0040]; pp.5, [0106]; pp.22, [0315], pp. 13, [0188]). Therefore, the apparatus taught by Wohlstadter et al. is capable of providing luminous material.

11. Regarding claims 7 and 14, Wohlstadter et al. disclose that the biological sample or analyte of interest may be a whole cell (pp.26, [0354]). It is inherent that the whole cell is viable since it is capable of undergoing electrochemiluminescence (ECL) reactions and assays (pp.2, [0023]; pp.2, [0029]). It is also noted that applicant does not appear to be claiming the sample as discussed above.

12. Regarding claim 8, Wohlstadter et al. teach a fibril mat acting as both a physical and optical filter (pp.28, [0370]) and disclose that the emitted and detected light generated by the triggered ECL emission may be emitted as non-visible radiation such

as infrared radiation (pp.15, [0211]). Therefore, the fibril mat is capable of filtering infrared radiation generated by the triggered ECL emission. See figure 29.

13. Regarding claim 10, Wohlstadter et al. teach a light detector or detectors that may be, for example, a photomultiplier tube (pp. 15, [0211]) and a digital computer (70) capable of performing the functions of a data counting unit (pp.22, [0314]). See also MPEP 2111-2114.

14. Regarding claim 11, Wohlstadter et al. teach deriving an analyte of interest from biological samples such as body fluids or tissues (pp.27, [0355]); shading the analyte of interest of the biological sample from external light by placing it in a housing (4717) or a light-tight box (pp.54, [0700]); impressing a magnetic field on the analyte of interest of the biological sample through support (10) (pp.12, [0172]) or a magnetic fibril mat (pp.12, [0171]); detecting luminescence by measuring electrochemiluminescence in a sample under ECL assay conditions (pp.2, [0029]).

15. Regarding claim 12, Wohlstadter et al. teach electrochemiluminescence methods for detecting or measuring an analyte of interest (abstract). An analyte of interest, as disclosed by Wohlstadter et al, may be a whole cell (pp. 26, [0354]) derived from body fluids or tissues (pp. 27, [0355]).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlstadter et al. (US 2001/0021534) in view of Kiontke (US 6,425,851).

Regarding claim 9, Wohlstadter et al. fail to teach a magnetic field generator that includes a signal generator and magnetic field generating coil.

Kiontke teaches a magnetic field generator including a signal generator as seen by the control unit (8) and a magnetic field coil (4) (column 7, lines 50-63).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the apparatus of Wohlstadter et al. to include a magnetic field coil and control unit as, for example, taught by Kiontke in order to enhance the ability of manipulating and controlling the magnetic field (Kiontke [abstract]) applied to the analyte of interest.

18. Claims 6 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlstadter et al. (US 2001/0021534) in view of Fong et al.

Wohlstadter et al. teach the limitations of which claim 12 depends as well as the step of maintaining the temperature (pp. 24, [0331]); the step of delivering ECL labeled binding reagents and/or analytes to discrete binding domains, wherein the binding reagent used may be a detectable agent, such as a fluorescent molecule (pp. 3, [0040];

pp.5, [0106]; pp.13, [[0188]); the step of using a fibril mat that allows gases to diffuse into, within and/or through the fibril mat (pp.18, [0262]) in order to provide gases into the microfluidics guides leading to the analyte of interest in the biological sample.

Wohlstadter et al. do not explicitly teach the method of providing oxygen and carbon dioxide to the analyte of interest in the biological sample. It is noted that Wohlstadter et al. teach the use of buffer solutions (pp.5, [0103]; pp.44, [0578], [0579], [0587], [0592]; pp.50, [0642]; pp.54, [0700]).

Fong et al. teach the method of adding 95% O_2:5% CO_2 to a buffer solution in order to maintain a physiological pH of the buffer solution (pp.1343, "*I_{sc} Measurement*").

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the invention of Wohlstadter et al. to include an explicit step of using oxygen and carbon dioxide in order to maintain a physiological pH of the buffer solutions.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ehnholm (US 6,535,755); Leland et al. (US 6,325,973); Massey et al. (5,798,083); Azure (US 2003/0233122); Fujiwara et al. (5,498,550); Lijestrand et al. (US 2003/0118477); Aizu et al. (4,950,070); Shibue et al.(5,240,863); Debad et al. (US 2004/0175695); Glezer et al. (US 2003/0113713); Wang et al. (US 6,537,211); Unger (US 6,403,056); Chance et al. (6,957,094); Kamholz et al. (US 2001/0017158).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Crystal I. Leach whose telephone number is 571-272-

5211. The examiner can normally be reached on Monday through Friday, 8 am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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